REMARKS

Claims 1, 3-5, 8-10, 13-15, 17-21 and 24-28 have been examined. Claims 8, 19 and 25 are hereby canceled by this Amendment without prejudice or disclaimer.

Claim Rejections - 35 U.S.C. § 102(b) - Yamamori et al.

The Examiner rejected claims 1, 5, 9-10, 13 and 17-18 as being anticipated by Yamamori et al. (US 5,957,127).

Yamamori relates to a capnometer fitted with an airway adaptor 1 (*see* FIG. 12). The adaptor includes a light source 3 and a light detector 7 for receiving light from the light source 3. (col. 1, lines 33-55). The airway adaptor 1 supports the light source 3 and the light detector 7 and includes a path for respiratory gas to pass through the light from the light source 3.

Claim 1 as recites, *inter alia*, a first guide member having two nasal prongs adapted to be inserted into the nostrils when the support member is located between the nostrils and the mouth for introducing the respiratory gas from the nostrils to the respiratory flow path.

In response to the rejection, Applicants submit Yamamori fails to disclose any nasal prongs. Rather, Yamamori only discloses a mask 24 fitted to an end of the airway adaptor 1.

Accordingly, Applicant submit that claim 1 is patentably distinguishable over Yamamori for at least this reason. Additionally, Applicants submit that claims 5 and 9 are allowable, at least because of their dependency from claim 1.

Regarding claim 10, the Examiner contends that the respiratory flow path (either part 2e or 1e is part of the support member and forms an interior surface of the support member. Thus,

the Examiner somehow concludes that the support member is disposed on an interior surface of the oxygen mask.

However, Applicants respectfully submit that in contrast to the Examiner rationalization, Yamamori clearly depicts that detecting portion 2 is disposed on the monitor body 9, which is located on the exterior of the mask 24. Thus, Applicants submit Yamamori fails to disclose a support member disposed on an interior surface of the oxygen mask as recited in claim 10.

Regarding claim 13, because this claim recites features similar to claim 1, Applicants submit claim 13 is patentably distinguishable over Yamamori for the same reasons set forth above with regard to claim 1.

Regarding claims 17 and 18, Applicants submit these claims are allowable, at least because of their dependencies from claims 1 and 13.

Claim Rejections - 35 U.S.C. § 102(b) - Fertig et al.

The Examiner rejected claims 1, 5, 9, 13-14 and 17-18 as being anticipated by Fertig et al. (US 5,095,900).

Fertig relates to a respiration monitor responsive to respired air from an endotracheal tube. (col. 1, lines 44-50). The respiration monitor of Fertig aids the determination of whether the tube has been properly introduced into the trachea and the esophagus. (col. 1, lines 10-15).

Consequently, as Fertig discloses that its sensor assembly receives air from the endotracheal tube (inserted via a person's mouth), Applicants submit Fertig fails to disclose "a first guide member having two nasal prongs adapted to be inserted into the nostrils when the support member is located between the nostrils and the mouth," as recited in claim 1.

Thus, Applicants submit claim 1 is patentably distinguishable over Fertig for at least this reason. Further, because claim 13 recites similar to the feature of claim 1 discussed above, Applicant submit claim 13 is patentably distinguishable over Fertig for the same reasons set forth above with regard to claim 1.

Additionally, Applicants submit claims 5, 9, 14 and 17-18 are allowable at least because of their dependencies from claims 1 and 13.

Claim Rejections - 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 5, 9, 13-15, 17-18, 20-21, 24 and 26 as being anticipated by O'Neil et al. (US 6,044,843).

O'Neil relates to a respiratory gas analyzer sensor 3 which connects to a gas analyzer. (col. 4, lines 2-5). The device utilizes an infrared photo-emitter 11 and photo-detector 13 over windows 17 to detect carbon dioxide levels. (col. 4, lines 33-37). An adapter 4 including a cuvette 2 portion is used to prevent the patient's respiratory gases from coming into contact with the respiratory gas sensor 3. (col. 3, line 66 - col. 4, line 3). Further, O'Neil discloses that the cuvette is designed to connect in series with tubing used to connect a patient to a mechanical ventilator or anesthesia breathing circuit. (col. 4, lines 7-9).

In view of O'Neil, Applicants respectfully submit, regarding independent claims 1, 13, and 21, that O'Neil fails to disclose: (1) "a support member . . . having a size adapted to be located between nostrils and a mount of the living body"; or (2) "a first guide member having two nasal prongs adapted to be inserted into the nostrils when the support member is located

between the nostrils and the mouth, for introducing the respiratory gas from the nostrils to the respiratory gas flow path.

In particular, as tubing is used to deliver the respiratory gases to the respiratory gas sensor 3, neither the sensor nor its elements have a size adapted to be located between nostrils and a mouth of the living body, nor is any guide member having nasal prongs disclosed.

Thus, Applicant submit claims 1, 13 and 21 are patentably distinguishable over O'Neil for at least these reasons. Additionally, Applicants submit that claims 5, 9, 13-15, 17-18, 20-21, 24 and 26 are allowable at least because of their dependency.

Claim Rejections - 35 U.S.C. § 103(a)

The Examiner rejected claims 3, 8 and 19 under § 103(a) as being unpatentable over Yamamori, Fertig or O'Neil, in further view of Dietz (US 5,005,571).

Dietz relates to a mouth nose mask for covering the mouth of a person and a nasal cannula used to sense inhalation. (col. 1, lines 20-30). Additionally, Dietz discloses a optoelectic inhalation sensor. (col. 6, lines 19-30; *see* FIG.15).

The Examiner contends that Yamamori, Fertig or O'Neil each disclose most of the features recited in claims 3, 8 and 19, but concedes they do not disclose the use of a mask with ear straps nor a guide member with nasal prongs. To compensate for this deficiency, the Examiner applies Dietz as disclosing a nasal cannula with prongs used with or without a mouth nose mask. (*citing* FIGS. 1 & 2; col. 2, lines 32-43).

However, because Dietz fails to compensate for the above noted deficiencies of Yamamori, Fertig and O'Neil as applied to claims 1 and 13, Applicants submit that claims 3, 8 and 19 are allowable, at least because of their dependency.

Claim Rejections - 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 3-5, 8-10, 13, 15, 17-21 and 24-28 as being unpatentable over O'Toole (US 6,379,312) in view of Passaro et al. (US 4,423,739).

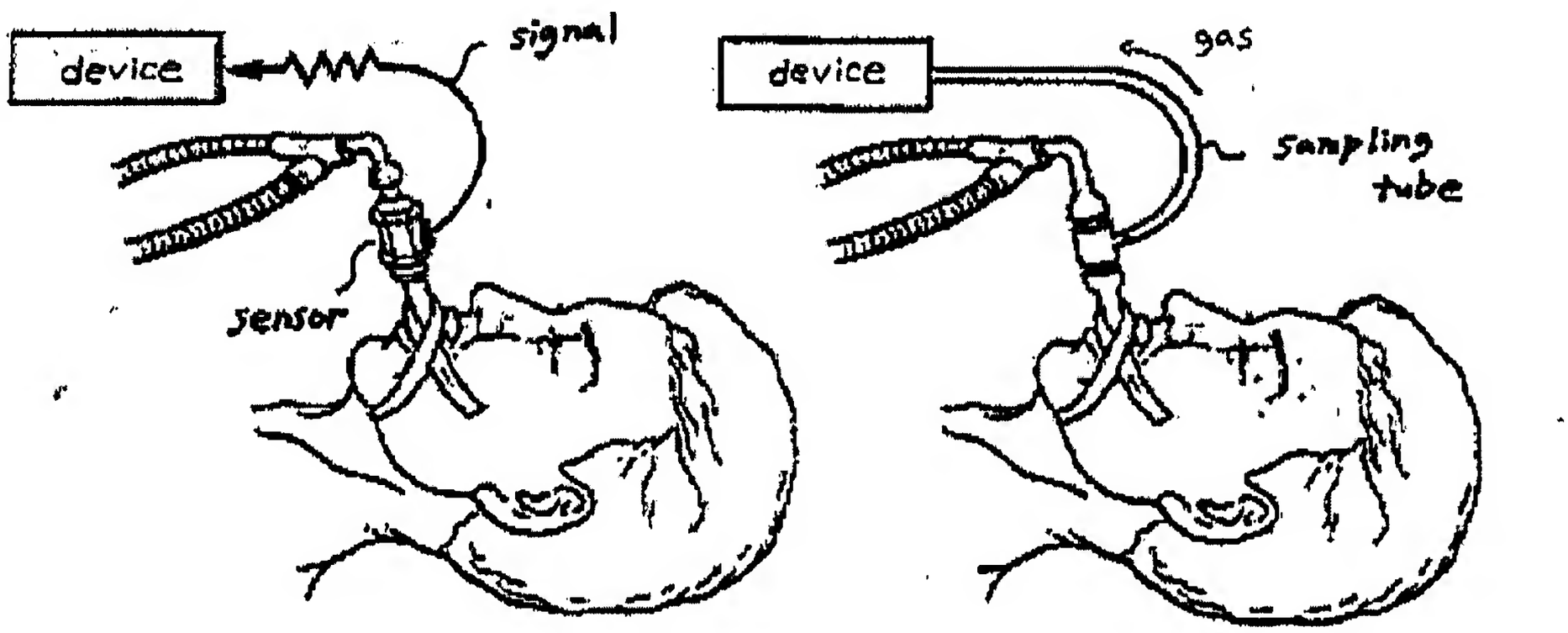
O'Toole relates to an end tidal carbon dioxide device coupled to a nasal cannula and oral tubes, which connect to the end tidal carbon dioxide analyzer by the use of a common outlet duct 26. (col. 3, lines 50-67; *see* FIG. 3). The sensing device is not depicted in proximity to either the nasal cannula or the oral tubes.

Passaro relates to an end tidal carbon dioxide gas analyzer which utilizes infrared energy from a source 11 transmitted through a gas sample cell 17 to a detector 21. The infrared energy is transmitted through windows 29. (col. 2, lines 22-34). Passaro further discloses that the patient's breath is conveyed to the inlet to the sample cell 17 by a suitable mask connection (not shown).

Applicants respectfully submit that even if combined as suggested by the Examiner the applied combination fails to disclose, at least, "a respiratory flow path formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located between the nostrils and the mouth ; and a first guide member having two nasal prongs adapted to be inserted into the nostrils when the support

member is located between the nostrils and the mouth, for introducing the respiratory gas from the nostrils to the respiratory gas flow path," as recited in claim 1.

As shown in Sketches 1 and 2, reproduced here, there are two ways to measure a concentration or presence/absence of carbon dioxide in respiratory gas. Sketch 1 shows a flow through method, and Sketch 2 shows a gas sampling method. The claimed invention is directed to the flow through method of sketch 1, whereas both of O'Toole and Passaro are directed to the gas sampling method in which the respiratory gas must be lead to a sample cell by way of a sampling tube and measurement is performed at the sample cell.



Sketch 1 Sketch 2

Passaro discloses a device performing such measurement. That is, the device must be connected to a sampling tube. On the other hand, O'Toole discloses a sampling tube which must be connected to such a device. In view of the description of Col. 2, Lines 34-37 and Col. 4, Lines 34-36 of Passaro, one ordinary skilled would not read Passaro as disclosing a respiratory

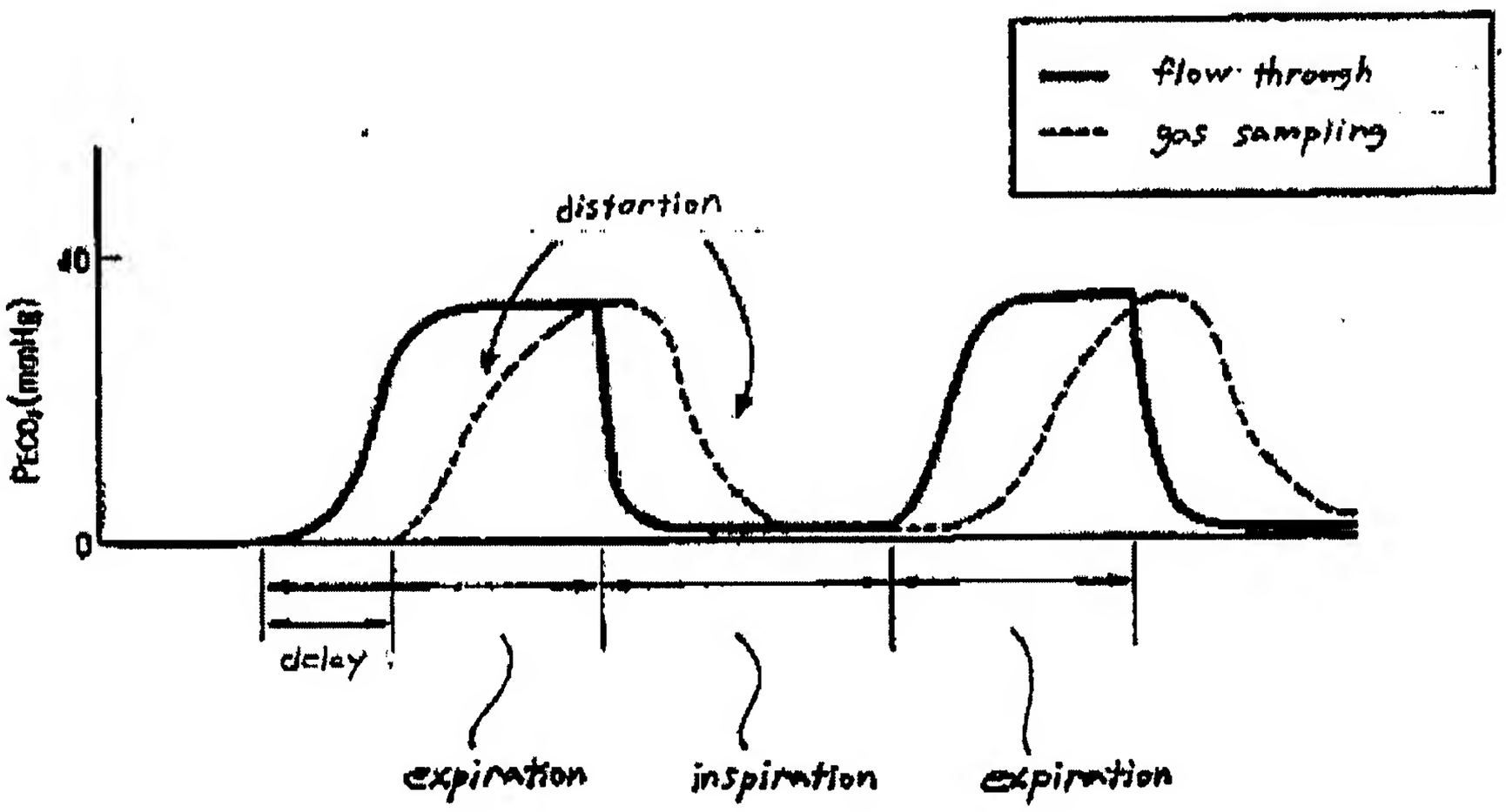
flow path formed in a support member so as to cross over the optical axis when the support member is located between the nostrils and the mouth (i.e., between the items 20 and 22 of O'Toole). Further, in order to combine the measurement device of Passaro with the item 20 of O'Toole corresponding to the claimed first guide member so as to meet the recitations of Claims 1, 13 and 21 (i.e., to obtain a configuration directed to the flow through method), it would change the principle of operation because both of O'Toole and Passaro are designed to perform the measurement according to the gas sampling method.

Thus, Applicants submit claims 1, 13 and 21 are patentably distinguishable over the applied combination for at least this reason.

Regarding claims 9, 17 and 24, Applicants submit the applied combination fails to disclose that the second guide member adapted to guide respiratory gas from the mouth is attached to the support member. Notably, since the device of Passaro corresponding to the claimed support member cannot be located between the nostrils and the mouth, the item 20 of O'Toole cannot be attached to the support member.

Further, as shown in Sketch 3 reproduced below, in the gas sampling method, because of the length of the sampling gas, the variation of the measured concentration of carbon dioxide always delays from the actual respirations, and the concentration profiles is somewhat distorted. Although the flow through method can avoid inconveniences caused by such delays and distortions, the conventional device performing the flow through method must be inserted into the mouth. Therefore, Applicants submit there is no prior art showing a device adapted to

perform the flow through method by guiding the respiratory gas from the nostrils to the respiratory flow path formed in the support member located between the nostrils and the mouth.



Sketch 3

Thus, Applicants submit claims 9, 17 and 24 are allowable for this additional reason.

Regarding claim 10, because neither O'Toole nor Passaro disclose "a support member supporting the light emitting element and the light receiving element such that they are opposed to each other on a single optical axis, the support member being disposed on an interior surface of the oxygen mask," we propose to argue that the applied combination fails to teach or suggest all the recited features.

In the rejection, the Examiner contends that Passaro discusses the response time of the device and how long the tubing between the mask device and the sensor increases the sensor's response time. However, we propose submitting the Examiner has mischaracterized the

reference. In particular, Passaro expressly discloses that in order to improve the response time "a very small gas sample cell is used." (col. 4, lines 20-25). Regarding the sampling catheter that delivers the respiratory gases from the patient's airway, Passaro discloses that a length of 3-8 feet is typically used. Consequently, Passaro does not suggest integrating the sensor into the mask device. In fact, Passaro does not even suggest shortening the length of the catheter to less than 3 feet in length.

Specifically, neither reference would lead one of ordinary skill to place a support member on the interior surface of a mask.

Thus, Applicants submit claim 10 is patentably distinguishable over the applied combination for at least this reason.

Regarding claims 3-5, 9-10, 13, 17-18, 20-21, 24 and 26-28, Applicants submit these claims are allowable at least because of their dependencies from claims 1, 10, 13 and 21.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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